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EXAMINER

MONSHIPOURI, MARYAM

ART UNIT

PAPER NUMBER

1652

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/493,887

Applicant(s)

Ettner et al.

Examiner

Maryam Monshipouri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.

4a) Of the above, claim(s) 4, 6-10, and 17-20 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-3, 5, and 11-16 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) Other: _____

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Claims 1-3, 5, and 11-16 are still at issue and are present for examination. Claims 4, 6-10 and 17-20 are withdrawn as drawn to non-elected inventions.

Applicants' arguments filed on 3/4/2002, paper No. 10, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

1. Claims 1-3, 5 and 11-16 are objected to because of the following informalities: Claim 1 and its dependent claims 2-3, 5 and 11-16 are objected because they refer to recombinant proteins and enzymes generically. In response to restriction requirement applicant elected (Group IV invention) directed to hydrogel comprising free radical scavenger proteins and methods of producing said hydrogel. However, in paper No.10, he/she still presents claim 1 generically. Appropriate correction is required. **Applicant is reminded that claim 1 is merely examined to the extent that proteins and enzymes are directed to free radical scavenger proteins and mimics thereof.**

2. Claim 3 is objected to because of the following informalities: “oraromatic” should be “aromatic”. Appropriate correction is required.

3. Claim 12 is objected to because of the following informalities: “comprising” in line 2, should **not** be capitalized. Appropriate correction is required.

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Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-3, 5 and 11-16 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As stated previously, the term “SOD/catalase enzyme mimic” in claim 1 and its dependent claims 2-3, 5 and 11-16 is indefinite. In traversal for this rejection applicant submits an article by Wang, entitled as “SOD Mimics”, in support of the fact that SOD mimics are a well understood term in the art. However, this article does not overcome said rejection because of the following reasons:

Firstly, the article merely attempts to define “SOD mimics” while claims 1 and its above mentioned dependent claims also recite “catalase mimics”. Thus, even if one assumes that said article defines the term “SOD mimics”, still no definition for “catalase mimics” is provided. Secondly, in page 5 of the article, Wang defines the properties of a transition metal complex as (1) having a low molecular weight and high cell permeability. It is not clear what is meant by “low” and “high” in said definition, as said terms are not absolute. Thirdly, applicant does not answer the question raised in the previous office action (i.e. Do claimed mimics have urea group for linking to PEG or not? And are they proteins? As in claim 5 applicants recites that “enzyme mimics and combinations thereof are used as proteins”. If the answer to the latter question is positive then it is

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not clear how the metalloporphyrins provided in Wang's article are proteins?). Fourthly, The examiner disagrees that "SOD/catalase mimics are well understood terms in the art. The examiner further maintains that enzyme mimics do not have a specific definition in the art and each laboratory defines them differently. Thus, providing an article written by Wang providing his view or opinion about "SOD mimics" does not overcome the previously drafted rejection.

6. Claims 1-3, 5, 11 and 14-16 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As mentioned previously the difference between "hydrogel" and "PEG" in claim 1 and its dependent claims 2-3, 5, 11 and 14-16 is unclear. The examiner proposed an amendment to claim 1 in order to clarify said confusion but the currently amended claim remains to be confusing. Claim 1 as written can lead to the interpretation that hydrogel and PEG are different products. However, specification suggests that by the term "hydrogel" applicant means PEG. Applicant is strongly advised to rewrite the claim to avoid confusion.

7. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 which depends from claim 1 recites the terms "SOD/catalase enzyme mimics" redundantly, as claim 1 already recites said term as one of the elements of the Markush.

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8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-3, 5 and 11-16 remain rejected under U.S.C. 103(a) as being unpatentable over Fortier (cited previously) in view of Galin cited previously further in view of current wound treatment/protection techniques according to previous office action. In traversal of this rejection applicant argues the following: **(a)** that Galin does not appear to relate to hydrogel or wound treatment and so there would be no motivation to use the teaching of Galin. **(b)** That even if it were assumed that Galin suggests linking via urea groups to PEG's and that there would be such motivation for such teachings to be applied to hydrogel, it is nowhere foreseen that such a linkage would result in a vastly improved gel formation time. **(c)** That according to the specification, prior art including Fortier have long gelation times between 20-270 minutes. Thus, the gel formation time due to linking proteins to PEG in the order of seconds, reported here (see fig 1) is far superior to those of prior art. Nothing in either reference suggests this surprising and important finding. Further, other benefits such as lack of formation of cleavage products and stability of protein linkage to activated PEG are obtained in this invention as compared to Fortier which render claims non-obvious over the combination of references.

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Finally, according to applicant, as generic claim 1 is allowable, non-elected claims should be rejoined with the elected invention and held allowable.

These arguments were fully considered but were found **unpersuasive**. With respect to applicant's **first** argument applicant is reminded that Galin reference was not cited for suggesting or relating to hydrogel (PEG) for wound treatment. Said reference was merely cited to indicate that diisocyanate has been used for activating PEG's of molecular weights similar to those of this invention, prior to this application. Had said reference taught about the hydrogel (PEG) comprising proteins for wound treatment said reference would have been 102 art against this invention. With respect to applicant's **second** argument he/she is reminded that this arguments can be merely applied to hydrogel (PEG) formation methods (claims 12-13) and not the hydrogel product (PEG) itself, as the time of formation of a product is irrelevant to said product. Further, the claimed process of making hydrogel does not recite any time limitations implying improvement over the methods of prior art. Thus, Fortier in view of Galin remains to render the process as claimed obvious because it meets all the limitations recited in process claim.

With respect to applicant's **third** argument the examiner would like to express her confusion. This is because, it is true that in figure 1 applicant demonstrate fast initial gel formation times of the order to seconds. However, the specification, page 25, indicates that complete crosslinking of the hydrogel occurs after 12 h storage at room temperature. Thus, it is not clear how 12 hours of complete reaction time (which is the rate limiting step in claimed gel formation method) is superior to those reported by Fortier which are of the order of 2 h.

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Further, the prior art with respect to hydrogel (PEG) formation indicates a lot of diversity with respect to gelation time) starting from gelation times of the order of seconds and ending in the order of hours or days) depending on the area of hydrogel (PEG) utility. It is also commonly known that the smaller the molecular weight of the PEG the faster the gelation time. Thus, gelation time can be optimized as a function of gel composition properties desired, such as mechanical durability, mesh size, heat stability, biodegradability etc. Hence, based on said information, hydrogel formation time by itself cannot be a novel and non-obvious characteristic of a gel unless the properties of the gel product (composition) provides some novel and non-obvious properties over the hydrogel of prior art.

With respect to other benefits of claimed gel formation method, it should be noted that Fortier recognized and recited drawbacks of hydrogel formation (such as instability, shape retention etc., see abstract and column 14) and it is said drawbacks that motivates one of ordinary skill, similar to instant inventors, to combine the teachings of Fortier with Galin as cited previously, to invent products and methods, such as those claimed instantly, in order to improve hydrogel (PEG) formation process and their products. In addition, applicant is reminded that even though the motivation of Fortier in view of Galin may not be identical to that of this invention, said combined teachings continue to render the claimed invention obvious, because obviousness does not require a single and unique motivation for arriving at an invention but merely that some reason to combine the cited references taught or suggested by the prior art.

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Finally, since generic claim 1 is not allowable , non-elected claims cannot be rejoined with the elected invention and they remain withdrawn.

No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (703) 308- 1083.

The Examiner can normally be reached daily from 8:30 A.M. to 5:00 P.M.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (703) 308-3804. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.



Maryam Monshipouri, Ph.D.

Patent Examiner